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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/636,163	08/07/2003	Thomas F. Fangrow JR.	ICUMM.127C1	3600
20995	7590	08/23/2004	EXAMINER	
KNOBBE MARTENS OLSON & BEAR LLP			TRAN, BINH Q	
2040 MAIN STREET			ART UNIT	
FOURTEENTH FLOOR			PAPER NUMBER	
IRVINE, CA 92614			3748	

DATE MAILED: 08/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/636,163	Applicant(s) FANGROW, THOMAS F.	
	Examiner BINH Q. TRAN	Art Unit 3748	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>08/23/2004</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Double Patenting

Claims 1-11 are rejected under the judicially created doctrine of double patenting over claims 1-8 of U. S. Patent No. 6,695,817 B1 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: *the application claims are merely broader than the patent claims.*

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 5-6, and 9 are rejected under 35 U.S.C. 102 (e) as being anticipated by Jepson et al. (Jepson) (Patent Number 5,797,897).

Regarding claim 1, Jepson discloses a medical valve (10) for selectively permitting fluid to flow between a first medical device and a second medical device (See Figures 1-8, 11-13), the valve comprising:

a housing having (40) an interface suitable for receiving a connector portion of the first medical device (12) (See Figures 1-8, 11-13); and

a seal made of a flexible material (e.g. 20, 52, 132), the seal having a downstream end in fluid communication with the interface, an upstream end suitable for receiving the second medical device, and a normally substantially closed passage (66) in fluid

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communication with the downstream end and the upstream end, the passage having a relatively wide in the region of the upstream end, the passage being a relatively small in the region of the downstream end, the passage adapted to have a relatively small interior volume when in an undisturbed state and a larger interior volume upon the introduction of the second medical device into the upstream end of the passage, the passage adapted to retract to define a restricted flow path and a relatively small interior volume upon the withdrawal of the second medical device from the seal, the upstream end initially being sealed as the second medical device is withdrawn, so that a fluid occupying the interior volume is forced toward the downstream end as the passage walls collapse (See Figures 1-8, 11-13; col. 6, lines 20-67).

Regarding claim 5, Jepson further discloses that the passage in the undisturbed state tapers inwardly from the upstream end to a region of minimum width (See Figures 1-8, 11-13; col. 6, lines 20-67).

Regarding claim 6, Jepson further discloses that the passage in the undisturbed state tapers outwardly from the region of minimum width toward the downstream end (See Figures 1-8, 11-13; col. 6, lines 20-67).

Regarding claim 9, Jepson further discloses that the a lead cannula attached to and in fluid communication with the interface extends from the interface into the downstream end of the seal, an end of the lead cannula being disposed within the passage at a location in the upstream direction from the furthest downstream periphery of the interior volume of the seal (See Figures 1-8, 11-13; col. 6, lines 20-67).

Claims 1, 5-6, and 9 are rejected under 35 U.S.C. 102 (e) as being anticipated by Lynn et al. (Lynn) (Patent Number 6,171,287 B1).

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Regarding claims 1 and 17, Lynn discloses a medical valve (1) for selectively permitting fluid to flow between a first medical device and a second medical device (See Figures 1, and 57-59), the valve comprising:

a housing having (12) an interface suitable for receiving a connector portion of the first medical device (32) (See Figures 69-70; col. 32, lines 51-60); and

a seal made of a flexible material (71), the seal having a downstream end in fluid communication with the interface, an upstream end suitable for receiving the second medical device, and a normally substantially closed passage (42) in fluid communication with the downstream end and the upstream end, the passage having a relatively wide in the region of the upstream end, the passage being a relatively small in the region of the downstream end, the passage adapted to have a relatively small interior volume when in an undisturbed state and a larger interior volume upon the introduction of the second medical device into the upstream end of the passage, the passage adapted to retract to define a restricted flow path and a relatively small interior volume upon the withdrawal of the second medical device from the seal, the upstream end initially being sealed as the second medical device is withdrawn, so that a fluid occupying the interior volume is forced toward the downstream end as the passage walls collapse (See Figure 1; col. 18, lines 12-67; col. 19, lines 1-35).

Regarding claim 5, Lynn further discloses that the passage in the undisturbed state tapers inwardly from the upstream end to a region of minimum width (See Figure 1; col. 18, lines 12-67; col. 19, lines 1-35).

Regarding claim 6, Lynn further discloses that the passage in the undisturbed state tapers outwardly from the region of minimum width toward the downstream end (See

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Figure 1; col. 18, lines 12-67; col. 19, lines 1-35).

Regarding claim 9, Lynn further discloses that the a lead cannula attached to and in fluid communication with the interface extends from the interface into the downstream end of the seal, an end of the lead cannula being disposed within the passage at a location in the upstream direction from the furthest downstream periphery of the interior volume of the seal (See Figure 1; col. 18, lines 12-67; col. 19, lines 1-35).

Allowable Subject Matter

Claims 2-4, 7-8, and 10-11 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Since allowable subject matter has been indicated, applicant is encouraged to submit formal drawings in response to this Office action. The early submission of formal drawings will permit the Office to review the drawings for acceptability and to resolve any informalities remaining therein before the application is passed to issue. This will avoid possible delays in the issue process.

Prior Art

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure and consists of three patents:

Lopez (Patent Number 5,700,248) discloses a medical valve has a body, which includes a wall structure defining an internal cavity having a proximal end and a distal end.

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Lynn (Patent Number 5,549,651) discloses a medical valve is provided that includes a housing having a main conduit and a branch extending from the main conduit and in fluid communication with it.

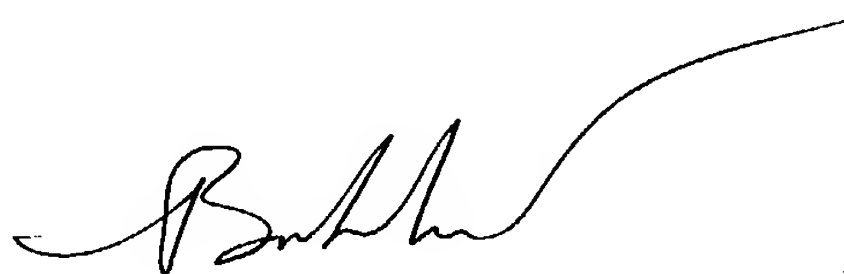
Atkinson et al. (Patent Number 5,533,708) discloses a medical coupling site, which is adapted to be attached directly to a standard male luer lock fitting.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Binh Tran whose telephone number is (703) 305-0245. The examiner can normally be reached on Monday-Friday from 8:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas E. Denion, can be reach on (703) 308-2623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0861.



BT
August 20, 2004

Binh Tran
Patent Examiner
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